

## **REMARKS**

Claims 47-76 have been canceled without prejudice or disclaimer. Claims 77-106 have been added and therefore are pending in the present application. Claims 77-106 are supported throughout the specification as filed, e.g., by the original claims.

It is respectfully submitted that the present amendment presents no new issues or new matter and places this case in condition for allowance. Reconsideration of the application in view of the above amendments and the following remarks is requested.

### **I. Information Disclosure Statement**

The Examiner states that the Information Disclosure Statement filed February 24, 2009 has not been considered because the cited references have not been provided. Applicants respectfully submit that the cited reference was submitted to the PTO via EFS-WEB on February 24, 2009 as evidenced, e.g., by the PTO's electronic acknowledgement provided to Applicants. Nevertheless, Applicants submit herewith a copy of the cited reference for the Examiner's convenience, and respectfully request the Examiner's consideration of the same.

### **II. Claim Objections**

Claims 47, 59, 60 and 76 stand objected to as reciting non-elected subject matter. This objection is respectfully traversed.

Claims 47, 59, 60 and 76 have been canceled, and claims 77-106 submitted herewith are directed to an isolated variant of a parent BLC RP-II protease, comprising a modification at position 144. Applicants respectfully submit that the objection is thereby obviated. Applicants respectfully request reconsideration and withdrawal of the rejection.

### **III. The Rejection of Claims 47, 59 and 60 under 35 U.S.C. 101 (Utility)**

Claims 47, 59 and 60 are rejected under 35 U.S.C. 101 as directed to non-statutory subject matter. This rejection is respectfully traversed.

As previously stated, the claims are directed to "variants" and thus, the present invention is not directed to products occurring in nature. Nevertheless, to expedite prosecution, the amended claims herewith are directed to isolated variants, thereby obviating the rejection.

For the foregoing reasons, Applicants submit that the claims overcome this rejection under 35 U.S.C. 101. Applicants respectfully request reconsideration and withdrawal of the rejection.

#### **IV. The Rejection of Claim 76 under 35 U.S.C. 112 (Indefiniteness)**

Claim 76 is rejected under 35 U.S.C. 112, second paragraph as allegedly being indefinite. This rejection is respectfully traversed.

Claim 76 has been canceled and new claim 106 recites “the variant” as requested by the Examiner.

For the foregoing reasons, Applicants submit that the claims overcome this rejection under 35 U.S.C. 112, second paragraph. Applicants respectfully request reconsideration and withdrawal of the rejection.

#### **V. The Rejection of Claims 47, 59, 60 and 76 under 35 U.S.C. 112 (Enablement)**

Claims 47, 59, 60 and 76 stand rejected under 35 U.S.C. 112, first paragraph as allegedly lacking enablement. This rejection is respectfully traversed.

It is well settled that “[t]he first paragraph of section 112 requires nothing more than objective enablement. How such a teaching is set forth, either by the use of illustrative examples or by broad terminology, is of no importance.” *In re Marzocchi*, 169 U.S.P.Q. 367, 369 (C.C.P.A. 1971). Moreover, “a specification disclosure which contains a teaching of the manner and process of making and using the invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented must be taken as in compliance with the enabling requirement of the first paragraph of section 112 unless there is reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support.” *In re Marzocchi*, 169 U.S.P.Q. at 369.

“The determination of what constitutes undue experimentation in a given case requires the application of a standard of reasonableness, having due regard for the nature of the invention and the state of the art ... The test is not quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed to enable the determination of how to practice a desired embodiment of the invention claimed ...” *Ex parte Jackson*, 217 U.S.P.Q. 804 (Bd. Pat. App. 1982).

It is also well settled that an assertion by the Patent Office that the enabling disclosure is not commensurate in scope with the protection sought must be supported by evidence or reasoning substantiating the doubts so expressed. *In re Dinh-Nguyen*, 181 U.S.P.Q. 46 (C.C.P.A. 1974). See also *U.S. v. Telectronics*, 8 U.S.P.Q.2d 1217 (Fed. Cir. 1988); *In re Bowen*, 181 U.S.P.Q. 48 (C.C.P.A. 1974); *Ex parte Hitzeman*, 9 U.S.P.Q.2d 1821 (BPAI 1988).

Factors to be considered in determining whether a disclosure would require undue experimentation include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. *In re Wands*, 8 U.S.P.Q.2d 1400, 1404 (Fed. Cir. 1988).

Applicants submit that the specification enables the claimed invention. The claimed invention is directed to an isolated variant of a parent BLC RP-II protease, comprising a modification at position 144 corresponding to the amino acid sequence of SEQ ID NO: 2, wherein the variant has RP-II protease activity. The specification contains an extensive disclosure of the variants of the present invention and methods for producing the polypeptides.

Application of the *Wands* factors to these facts further supports the conclusion that the claims are enabled. First, the present invention is in the field of molecular biology. The *Wands* court has already held that the level of skill in this art is high. *Wands*, 858 F.2d at 740. Second, the specification provides an extensive disclosure for producing the claimed polypeptide. Third, as in *Wands*, the methods of making the claimed polypeptides and screening for RP-II protease activity are known in the art and described in the specification. Fourth, the specification discloses parent BLC RP-II proteases and numerous variants within the scope of the claims. Fifth, given the extensive guidance given in the specification and the high level of skill in the art, the experimentation involved to produce other variants within the scope of the claims is routine and well within the skill of those in the art. As held by the *Wands* court, "The test is not merely quantitative since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experiment should proceed." *Id.* at 737.

As of Applicants' effective filing date, persons of ordinary skill in the art were able to routinely produce BLC RP-II protease variants comprising a modification at position 144. Moreover, the specification discloses a number of other positions which can be mutated.

For the foregoing reasons, Applicants submit that the claims overcome this rejection under 35 U.S.C. 112, first paragraph (enablement). Applicants respectfully request reconsideration and withdrawal of the rejection.

## **VI. The Rejection of Claims 47, 59, 60 and 76 under 35 U.S.C. 112 (Written Description)**

Claims 47, 59, 60 and 76 stand rejected under 35 U.S.C. 112, first paragraph, as allegedly containing subject matter which was not described in the specification in a way to reasonably convey to one skilled in the art that the inventors, at the time the application was filed, had possession of the claimed invention. This rejection is respectfully traversed.

In response to Applicants' prior arguments in an analogous rejection, the Examiner acknowledges that the specification describes a number of positions that can be modified but states that the claims encompass any protein having any structure and having glutamic-acid-specific endopeptidase activity. The Examiner contends that description of said positions fails to describe the full scope of any protein having any structure and having glutamic-acid-specific endopeptidase activity in a manner such that the skilled artisan would recognize that Applicants were in possession of the full scope of the invention. Applicants respectfully disagree, and submit that the specification complies with the written description requirement.

As set forth in Federal Circuit decisions, a specification complies with the written description requirement if it provides "a precise definition, such as by structure, formula, chemical name, or physical properties of the claimed subject matter sufficient to distinguish it from other materials." See, e.g., *University of California v. Eli Lilly and Co.*, 43 U.S.P.Q.2d 1398, 1404 (Fed. Cir. 1997); *Enzo Biochem v. Gen-Probe Inc.*, 63 U.S.P.Q.2d 1609, 1613 (Fed. Cir. 2002). The written description requirement necessitates that the applicant "convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention." *Vas-Cath, Inc. v. Mahurkar*, 19 USPQ2d 1111, 1116 (Fed. Cir. 1991). There is a strong presumption that an adequate written description of the claimed invention is present when the application is filed. See *In re Wertheim*, 191 USPQ 90, 97 (CCPA 1976).

Applicants' amended claims are directed to an isolated variant of a parent BLC RP-II protease, comprising a modification at position 144 corresponding to the amino acid sequence of SEQ ID NO: 2, wherein the variant has RP-II protease activity. The specification describes a number of other positions, including specific mutations, which can be combined with any of the claimed modification. As such, Applicants submit that the structure, i.e., an isolated variant of a parent BLC RP-II protease comprising a modification at position 144, and the function, i.e., RP-II protease activity, are sufficiently described such that the skilled artisan would recognize that Applicants were in possession of the full scope of the invention.

For the foregoing reasons, Applicants submit that the claims overcome this rejection under 35 U.S.C. 112. Applicants respectfully request reconsideration and withdrawal of the rejection.

**VII. The Rejection of Claims 47 and 76 under 35 U.S.C. 102**

Claims 47 and 76 stand rejected under 35 U.S.C. 102(b) as allegedly being anticipated by Norregaard-Madsen et al. (WO 01/16285). This rejection is respectfully traversed.

Norregaard-Madsen et al. disclose RP-II proteases and variants thereof. However, Norregaard-Madsen et al. do not disclose BLC RP-II proteases, comprising a modification at position 144, as claimed herein.

For the foregoing reasons, Applicants submit that the claims overcome this rejection under 35 U.S.C. 102(b). Applicants respectfully request reconsideration and withdrawal of the rejection.

**VIII. The Rejection of Claims 47 and 59 under 35 U.S.C. 102**

Claims 47 and 59 stand rejected under 35 U.S.C. 102(b) as being anticipated by Sloma et al. (*J. Bacteriol.* 172: 1024-1029 (1990)). This rejection is respectfully traversed.

Sloma et al. disclose a wild-type metalloprotease from *Bacillus subtilis*. However, Sloma et al. do not disclose BLC RP-II proteases, comprising a modification at position 144, as claimed herein.

For the foregoing reasons, Applicants submit that the claims overcome this rejection under 35 U.S.C. 102(b). Applicants respectfully request reconsideration and withdrawal of the rejection.

**IX. The Rejection of Claims 47 and 59 under 35 U.S.C. 102**

Claims 47 and 59 stand rejected under 35 U.S.C. 102(a&e) as being anticipated by Ostergaard et al. (U.S. Patent No. 6,558,939). This rejection is respectfully traversed.

Ostergaard et al. is a US equivalent to Norregaard-Madsen et al. discussed in Section VI above. As explained therein, Ostergaard et al. do not disclose BLC RP-II proteases, comprising a modification at position 144, as claimed herein.

For the foregoing reasons, Applicants submit that the claims overcome this rejection under 35 U.S.C. 102(a&e). Applicants respectfully request reconsideration and withdrawal of the rejection.

**IX. The Rejection of Claim 76 under 35 U.S.C. 103**

Claim 76 stands rejected under 35 U.S.C. 103 as being unpatentable over Sloma et al., 1990 or Ostergaard et al, 2003 in view of Norregaard-Madsen et al, 2001. The Examiner states

that detergent compositions comprising proteases are well-known in the art. This rejection is respectfully traversed.

The teachings of Sloma et al. and Ostergaard et al. are discussed above. For at least the reasons that the instantly claimed variants are not anticipated by the disclosure of Sloma et al. and/or Ostergaard et al., nor does the disclosure thereof render obvious the pending claim to detergent compositions comprising these variants.

For the foregoing reasons, Applicants submit that the claims overcome this rejection under 35 U.S.C. 103. Applicants respectfully request reconsideration and withdrawal of the rejection.

#### **XI. Conclusion**

In view of the above, it is respectfully submitted that all claims are in condition for allowance. Early action to that end is respectfully requested. The Examiner is hereby invited to contact the undersigned by telephone if there are any questions concerning this amendment or application.

All required fees were charged to Novozymes North America, Inc.'s Deposit Account No. 50-1701 at the time of electronic filing. The USPTO is authorized to charge this Deposit Account should any additional fees be due.

Respectfully submitted,

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